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EXAMINER
SMITH, L

ART UNIT	PAPER NUMBER
1813	16

18N1/1118

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DATE MAILED: 11/18/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☐ This application has been examined ☒ Responsive to communication filed on 9/6/94 ☒ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474..
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-18 are pending in the application.

   Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1-18 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

15. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

16. The examiner acknowledges receipt of the amendment and exhibits.

17. Applicant's arguments filed 9/6/94 have been fully considered but they are not deemed to be persuasive.

18. The rejection of claims 1-18 under 35 U.S C. §112 first paragraph as the disclosure is enabling only for claims limited to a method of immunizing vertebrate by administering a DNA transcription unit encoding H1 and H7 influenza hemagglutinin antigens in nonhuman animals is maintained essentially for reasons set forth in paper no. 12, paragraph 19 of the previous office action. Applicant urges that the H1 and H7 influenza hemagglutinin antigens are representative of the antigens which can be used in the invention and were not intended to induce protection to other hemagglutinin subtypes. It is the examiner's position that the claims are broadly drawn to a method of immunizing a mammal, including humans, against influenza virus by administering the DNA transcription unit. The examiner interprets the claims to read on all strains and subtypes of influenza antigen. The specification lacks description of the effectiveness of the immunization method in protecting mammals, including humans, against strains and subtypes of influenza other than H1 and H7 and it appears from applicant's response that one

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would not reasonably expect cross-reactivity. Therefore it is not clear that the specification is commensurate in scope with the claims.

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19. The rejection of claims 1-4 under 35 U.S.C. §103 as being unpatentable over King is maintained essentially for reasons set forth in paper no. 12, paragraph 20 of the previous office action. Applicant urges that King describes injection of a construct containing the gene for gp120 for the production of cytotoxic T cells in mice and that mice do not develop AIDS upon being infected with HIV and that this model cannot be used to test for protective immunization. It is the examiner's position that King states that this is a novel techniques because it uses naked plasmid DNA or mRNA to produce the MHC class I restricted cytotoxic T cell response. Therefore one would reasonably expect this novel technique to be effective in generating cellular as well as cell-mediated immune responses against HIV that would be protective. Additionally, King suggests this technique for the development of therapeutics and preventatives not only against HIV, but herpes, hepatitis, cancer and rheumatoid arthritis as well. Obviousness does not require absolute predictability (see In re Merck and Company, Inc. 800 F.2d 1091, 231 USPQ 375 Fed. Cir. 1986; In re Lamberti, 545 F.2d 747, 192 USPQ 278 CCPA 1976;In re Miegel et al. 159 USPQ 716; and In re Moreton 129 USPQ 288), but only a reasonable expectation of success (see In

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re Longi 225 USPQ 645; In re Pantzer et al. 144 USPQ 415; and In re Farnham et al. 188 USPQ 365). Moreover, limitations such as route of administration do not appear in claims 1-4.

20. The rejection of claims ~~5-18~~ 7-14, 17, 18 under 35 U.S.C. §103 as being unpatentable over WO 90/11092 in view of Huylebroeck et al is maintained essentially for reasons set forth in paper no.12, paragraphs 21 and 22 of the previous office action. Applicant urges that neither Huylebroeck nor WO 90/11092 provide motivation to combine the references, neither teaches nor suggests the claimed invention and applicant appears to argue the references individually without clearly addressing the combination of teachings. It is the examiner's position that it should be noted that the claims are drawn to a method of immunizing a mammalian host with the claimed DNA transcription unit. The claims are not drawn to a method of producing hemagglutinin. Given the concern and focus in the art on effective vaccines against influenza and given the well known fact that the major response to influenza infection is directed to the immunodominant hemagglutinin molecule, one would be motivated, by these two well known facts alone, to include, in a DNA transcription unit (taught by Huylebroeck et al) the gene for the hemagglutinin molecule as part of a method of delivering polynucleotides into a cell (as taught by WO 90/11092) with the expectation of generating protective immune responses against influenza. Specific

statements in the references themselves which would spell out the claimed invention are not necessary to show obviousness since questions of obviousness involves not only what references expressly teach, but what they would collectively suggest to one of ordinary skill in the art. See CTS Corp. v. Electro Materials Corp. of America (DC SNY) 202 USPQ 22; and In re Burckel (CCPA 201 USPQ 67).

21. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

22. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO FAX Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in

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the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 FAX Center number is (703) 305-3014. The hours of operation of the center are 8:45 am - 4:45 pm, Monday - Friday.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynette F. Smith whose telephone number is (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Smith/lfs LFS
November 15, 1994

CHRISTINE M. NUCKER
SUPERVISORY PATENT EXAMINER
GROUP 180

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